

Exhibit L



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 2008

Bard Peripheral Vascular, Inc.
c/o Genevieve Balutowski, RAC
Associate Project Manager, Regulatory Affairs
1625 West 3rd Street
P.O. Box 1740
Tempe, AZ 85280

Re: K080668

Trade/Device Name: G2 Express Filter System – Femoral Delivery Kit and
G2 Express Filter System –Jugular/Subclavian Delivery Kit

Regulation Number: 21 CFR 870.3375

Regulation Name: Cardiovascular intravascular filter

Regulatory Class: Class II

Product Code: DTK

Dated: July 2, 2008

Received: July 3, 2008

Dear Ms. Balutowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or

Page 2 – Ms. Genevieve Balutowski

any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Special 510(k)

G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits Page 120

Indications for Use

510(k) Number (if known):

Device Name: G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits

Indications for Use:

The G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits are indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.
- G2 EXPRESS™ Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)


Concurrence of CDRII, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K080668

Page 1 of 1

Bard Peripheral Vascular, Inc.

TRADE SECRET/CONFIDENTIAL INFORMATION
Notify CR Bard Before Releasing this Document.

BARD